

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

| | | | | | | | |
|---|---|----------------------------|----------------------------|---|------|-------|----------|
| <input type="checkbox"/> Initial Application <input type="checkbox"/> Survey <input type="checkbox"/> Change in Certification Type <input checked="" type="checkbox"/> Other Changes (Specify) <u>Medical Director Change</u> | CLIA IDENTIFICATION NUMBER <u>99 D 0968792</u> (If an initial application leave blank, a number will be assigned) | | | | | | |
| FACILITY NAME <u>Gamma-Dynacare Medical Laboratories</u> | FEDERAL TAX IDENTIFICATION NUMBER | | | | | | |
| EMAIL ADDRESS <u>lindner1@gamma-dynacare.com</u> | TELEPHONE NO. (include area code) FAX NO. (include area code) <u>519-679-1630</u> <u>519-640-1225</u> | | | | | | |
| FACILITY ADDRESS — Physical Location of Laboratory (Building, Floor, Suite if applicable.) Fee Coupon/Certificate will be mailed to this Address unless mailing address is specified | MAILING/BILLING ADDRESS (if different from street address) | | | | | | |
| NUMBER, STREET (No P.O. Boxes) <u>245 Pall Mall Street</u> | NUMBER, STREET | | | | | | |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">CITY <u>London, Ontario</u></td> <td style="width: 33%;">STATE <u>Canada</u></td> <td style="width: 33%;">ZIP CODE <u>N6A 1P4</u></td> </tr> </table> | CITY <u>London, Ontario</u> | STATE <u>Canada</u> | ZIP CODE <u>N6A 1P4</u> | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">CITY</td> <td style="width: 33%;">STATE</td> <td style="width: 33%;">ZIP CODE</td> </tr> </table> | CITY | STATE | ZIP CODE |
| CITY <u>London, Ontario</u> | STATE <u>Canada</u> | ZIP CODE <u>N6A 1P4</u> | | | | | |
| CITY | STATE | ZIP CODE | | | | | |
| NAME OF DIRECTOR (Last, First, Middle Initial) <u>Li, Hui</u> | FOR OFFICE USE ONLY Date Received | | | | | | |

II. TYPE OF CERTIFICATE REQUESTED (Check only one)

- Certificate of Waiver (Complete Sections I – VI and IX – X)
- Certificate for Provider Performed Microscopy Procedures (PPM) (Complete Sections I – X)
- Certificate of Compliance (Complete Sections I – X)
- Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes
- | | | |
|---|-------------------------------|-------------------------------|
| <input type="checkbox"/> The Joint Commission | <input type="checkbox"/> AOA | <input type="checkbox"/> AABB |
| <input checked="" type="checkbox"/> CAP | <input type="checkbox"/> COLA | <input type="checkbox"/> ASHI |

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA requirements. Proof of these requirements for the laboratory director must be submitted with the application.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0581. The time required to complete this information collection is estimated to average 30 minutes to 2 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, Attn: PRA Reports Clearance Officer, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

III. TYPE OF LABORATORY (Check the one most descriptive of facility type)

- | | | |
|--|--|--|
| <input type="checkbox"/> 01 Ambulance | <input type="checkbox"/> 11 Health Main. Organization | <input type="checkbox"/> 22 Practitioner Other (Specify) |
| <input type="checkbox"/> 02 Ambulatory Surgery Center | <input type="checkbox"/> 12 Home Health Agency | |
| <input type="checkbox"/> 03 Ancillary Testing Site in Health Care Facility | <input type="checkbox"/> 13 Hospice | <input type="checkbox"/> 23 Prison |
| <input type="checkbox"/> 04 Assisted Living Facility | <input type="checkbox"/> 14 Hospital | <input type="checkbox"/> 24 Public Health Laboratories |
| <input type="checkbox"/> 05 Blood Bank | <input checked="" type="checkbox"/> 15 Independent | <input type="checkbox"/> 25 Rural Health Clinic |
| <input type="checkbox"/> 06 Community Clinic | <input type="checkbox"/> 16 Industrial | <input type="checkbox"/> 26 School/Student Health Service |
| <input type="checkbox"/> 07 Comp. Outpatient Rehab Facility | <input type="checkbox"/> 17 Insurance | <input type="checkbox"/> 27 Skilled Nursing Facility/ Nursing Facility |
| <input type="checkbox"/> 08 End Stage Renal Disease Dialysis Facility | <input type="checkbox"/> 18 Intermediate Care Facility for Mentally Retarded | <input type="checkbox"/> 28 Tissue Bank/Repositories |
| <input type="checkbox"/> 09 Federally Qualified Health Center | <input type="checkbox"/> 19 Mobile Laboratory | <input type="checkbox"/> 29 Other (Specify) |
| <input type="checkbox"/> 10 Health Fair | <input type="checkbox"/> 20 Pharmacy | |
| | <input type="checkbox"/> 21 Physician Office | |
- Is this a shared lab? Yes No

IV. HOURS OF LABORATORY TESTING (List times during which laboratory testing is performed in HH:MM format)

| | SUNDAY | MONDAY | TUESDAY | WEDNESDAY | THURSDAY | FRIDAY | SATURDAY |
|-------|--------|--------|---------|-----------|----------|--------|----------|
| FROM: | 07:00 | 07:00 | 07:00 | 07:00 | 07:00 | 07:00 | 07:00 |
| TO: | 21:00 | 24:00 | 24:00 | 24:00 | 24:00 | 24:00 | 24:00 |

(For multiple sites, attach the additional information using the same format.)

V. MULTIPLE SITES (must meet one of the regulatory exceptions to apply for this provision)

Are you applying for the multiple site exception?

- No. If no, go to section VI. Yes. If yes, complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

- Is this a laboratory that has temporary testing sites?

Yes No
- Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?

Yes No

If yes, provide the number of sites under the certificate _____ and list name, address and test performed for each site below.
- Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?

Yes No

If yes, provide the number of sites under this certificate _____ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here and attach the additional information using the same format.

| NAME AND ADDRESS/LOCATION | | TESTS PERFORMED/SPECIALTY/SUBSPECIALTY |
|---|-----------------------------------|--|
| NAME OF LABORATORY OR HOSPITAL DEPARTMENT | | |
| ADDRESS/LOCATION (Number, Street, Location if applicable) | | |
| CITY, STATE, ZIP CODE | TELEPHONE NO. (include area code) | |
| NAME OF LABORATORY OR HOSPITAL DEPARTMENT | | |
| ADDRESS/LOCATION (Number, Street, Location if applicable) | | |
| CITY, STATE, ZIP CODE | TELEPHONE NO. (include area code) | |

In the next three sections, indicate testing performed and annual test volume.

VI. WAIVED TESTING

Identify the waived testing performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory.

e.g. (Rapid Strep, Acme Home Glucose Meter)

Indicate the estimated **TOTAL ANNUAL TEST** volume for all waived tests performed _____

Check if no waived tests are performed

VII. PPM TESTING

Identify the PPM testing performed. Be as specific as possible.

e.g. (Potassium Hydroxide (KOH) Preps, Urine Sediment Examinations)

Indicate the estimated **TOTAL ANNUAL TEST** volume for all PPM tests performed _____

For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the "total estimated test volume" in section VIII.

Check if no PPM tests are performed

If additional space is needed, check here and attach additional information using the same format.

VIII. NON-WAIVED TESTING (Including PPM testing)

If you perform testing other than or in addition to waived tests, complete the information below. If applying for one certificate for multiple sites, the total volume should include testing for ALL sites.

Place a check (✓) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the information included with the application package.)

If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the applicable specialty/subspecialty for which you are accredited for CLIA compliance. (The Joint Commission, AOA, AABB, CAP, COLA or ASHI)

| SPECIALTY/SUBSPECIALTY | ACCREDITING ORGANIZATION | ANNUAL TEST VOLUME | SPECIALTY/SUBSPECIALTY | ACCREDITING ORGANIZATION | ANNUAL TEST VOLUME |
|--|--------------------------|--------------------|--|--------------------------|--------------------|
| HISTOCOMPATIBILITY | | | HEMATOLOGY | | 4400 |
| <input type="checkbox"/> Transplant | | | <input checked="" type="checkbox"/> Hematology | CAP, OLA | |
| <input type="checkbox"/> Nontransplant | | | IMMUNOHEMATOLOGY | | |
| MICROBIOLOGY | | | <input type="checkbox"/> ABO Group & Rh Group | | |
| <input type="checkbox"/> Bacteriology | | | <input type="checkbox"/> Antibody Detection (transfusion) | | |
| <input type="checkbox"/> Mycobacteriology | | | <input type="checkbox"/> Antibody Detection (nontransfusion) | | |
| <input type="checkbox"/> Mycology | | | <input type="checkbox"/> Antibody Identification | | |
| <input type="checkbox"/> Parasitology | | | <input type="checkbox"/> Compatibility Testing | | |
| <input type="checkbox"/> Virology | | | PATHOLOGY | | |
| DIAGNOSTIC IMMUNOLOGY | | 634,700 | <input type="checkbox"/> Histopathology | | |
| <input type="checkbox"/> Syphilis Serology | | | <input type="checkbox"/> Oral Pathology | | |
| <input checked="" type="checkbox"/> General Immunology | | | <input type="checkbox"/> Cytology | | |
| CHEMISTRY | | 6,327,381 | RADIOBIOASSAY | | |
| <input checked="" type="checkbox"/> Routine | CAP, OLA | | <input type="checkbox"/> Radiobioassay | | |
| <input checked="" type="checkbox"/> Urinalysis | CAP, OLA | | CLINICAL CYTOGENETICS | | |
| <input checked="" type="checkbox"/> Endocrinology | CAP, OLA | | <input type="checkbox"/> Clinical Cytogenetics | | |
| <input checked="" type="checkbox"/> Toxicology | CAP, OLA | | TOTAL ESTIMATED ANNUAL TEST VOLUME | | |

IX. TYPE OF CONTROL

VOLUNTARY NONPROFIT

- 01 Religious Affiliation
- 02 Private Nonprofit
- 03 Other Nonprofit

(Specify)

FOR PROFIT

- 04 Proprietary

GOVERNMENT

- 05 City
- 06 County
- 07 State
- 08 Federal
- 09 Other Government

(Specify)

X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

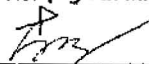
| CLIA NUMBER | NAME OF LABORATORY |
|-------------|--------------------|
| | |
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| | |

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY (Sign in ink)



DATE

Oct 30 / 2013